

WHAT WE CLAIM IS :

1. An oral lipid lowering pharmaceutical unit form comprising a first solid or semi solid composition comprising fenofibrate and a second
5 solid or semi solid composition comprising at least a homocysteine lowering agent, the second composition being a modified release form
2. The pharmaceutical composition according to claim 1 characterised that it comprises an effective amount fenofibrate for the treatment of
10 hyperlipidemia.
3. The pharmaceutical composition according to claim 1, in which the homocysteine lowering agent is selected from the group consisting of folic acid, vitamin B12, vitamin B6, Betaine, and mixtures thereof.
4. The pharmaceutical composition according to claim 1, in which the
15 amount of Fenofibrate is comprised between 25mg and 400mg, preferably between 50mg and 300mg.
5. The pharmaceutical composition according to claim 1 in which the Fenofibrate is present in mixture with at least one polyglyceride.
6. The pharmaceutical composition according to claim 5 in which the
20 Fenofibrate is present under the form of micronized Fenofibrate.
7. The pharmaceutical composition according to claim 1 from which the modified release of the homocysteine lowering agent is either delayed or extended or any combination of these releases.
8. The pharmaceutical composition according to claim 1 wherein the
25 homocysteine lowering agent is folic acid.

9. The pharmaceutical composition of claim 1, in which the first composition is an substantially immediate release composition of fenofibrate.
- 5 10. The pharmaceutical composition according to claim 1 , wherein the dose of fenofibrate is between 50 and 300 mg and the dose of the homocysteine lowering agent is between 0.001 and 100 mg.
11. The pharmaceutical composition according to claim 1 where the single unit form is a hard gelatin, hypromellose capsule or any other pharmaceutically acceptable capsule.
- 10 12. The pharmaceutical composition according to claim 1 where the single unit form is a tablet.
13. The pharmaceutical composition according to claim 1 wherein homocysteine lowering agent is an extended release form.
- 15 14. The pharmaceutical composition according to claim 1 wherein the second composition is a composition combining an immediate release form of a part of the homocysteine lowering agent with a prolonged release form of another part of the homocysteine lowering agent.
- 20 15. The pharmaceutical composition according to claim 1, in which the second composition is a composition controlling the release of the homocysteine lowering agent so as to ensure, after single dose adfministration of the composition to human volunteers a Tmax (time for reaching the maximum peak concentration in the human plasma) in vivo of between 1 and 10 hours, preferably between 2 and 8
25 hours, more preferably between 2 and 6 hours.
16. The pharmaceutical composition according to claim 1, in which the second composition is a composition controlling the release of the

homocysteine lowering agent so as to ensure a dissolution rate in vitro, on a paddle dissolution apparatus (EP 2003, 4th edition, 2.9.3) at 100 round per minute (rpm) in a 7.5 phosphate buffer, of 0 to 50 % after 30 minutes, 5 to 75 % after 1 hour, 20 to 95 % after 2 hours, 50-95 % after 4 hours and more than 80 % after 8 hours.

- 5 17. The pharmaceutical composition according to claim 1 wherein the homocysteine lowering agent is a mix of two or more of said substances.
- 10 18. The pharmaceutical composition according to claim 1, wherein the final form is a capsule containing fenofibrate as a paste and folic acid as coated, uncoated or bilayer -modified release tablet.
- 15 19. The pharmaceutical composition according to claim 1, wherein the first solid or semi solid composition comprising a fibrate derivative is substantially free of homocysteine lowering agent and/or the second solid or semi solid composition comprising at least a homocysteine lowering agent is substantially free of fibrate derivative.
20. The pharmaceutical composition according to claim 18, further containing vitamine B12 in a modified release form
- 20 21. The pharmaceutical composition according to claim 14, further containing vitamin B12 in an extended release form